Section XII: 510(k) Summary of Safety and Effectiveness

SAFE MEDICAL DEVICES ACT OF 1990

510(k) Summary

NAME OF FIRM:
I.T.S. Implantat-Technologie-Systeme GmbH.
Autal 28.
Lassnitzhoehe A – 8301
AUSTRIA

FEB - 2 2007

510(k) FIRM CONTACT:
Al Lippincott
Engineering Consulting Services, Inc.
3150 E. 200th St.
Prior Lake, MN 55372

TRADE NAME: Fibula Plate PROlock with Angular Stability

COMMON NAME: Bone Plate System

CLASSIFICATION: Plate, Fixation, Bone

(see 21 CRF, Sec. 888.3030).

DEVICE PRODUCT CODE: HRS

SUBSTANTIALLY EQUIVALENT DEVICES
Synthes Semi-Tubular Plate **(Pre – Amendment)**
Synthes Small Fragment System **(K000684)**
Synthes 4.5mm LCP Straight Reconstruction Plates **(K051986)**
Synthes LCP Distal Tibia Plates **(K013248)**
Synthes One-Third Tubular DCL Plate **(K011335)**
Synthes Curved Reconstruction Plate **(K011334)**
Synthes Medial Distal Tibia Plates **(K001945)**
Zimmer Periarticular Plating System **(K040593)**
Acumed Lower Extremity Congruent Plate System **(K033639)**

DEVICE DESCRIPTION: The I.T.S. Fibula Plate PROlock with Angular Stability is a low-profile left and right titanium plate in three lengths with various length cortical and/or cancellous locking self-tapping stabilization screws. The fibula plate is made from CP Titanium according to ASTM F 67-00 and the screws are made from 6-4 Alloyed Titanium according to ASTM F 136-02. The plate and screws are surface conditioned with a TIODIZE, Type II preparation.

INTENDED USE: The I.T.S. Fibula Plate PROlock with Angular Stability is a titanium implant fracture fixation system for repairing bone fractures located from the middle to the distal third of the fibula. Indications for Use include metaphysial and diaphysial fracture fixation of acute fractures, malunions, and non-unions of the distal fibula. Other indications include corrective osteotomy and open and closed fractures.

The system is not intended for spinal use.

BASIS OF SUBSTANTIAL EQIVLAENCE: The I.T.S. Fibula Plate PROlock with Angular Stability is substantially equivalent to the Pre-Amendment Synthes, current Synthes, Zimmer , and Acumed bone plate systems.

SUMMARY OF SAFETY AND EFFECTIVENESS: The I.T.S. Fibula Plate PROlock with Angular Stability is shown to be safe and effective for use in fracture fixation of bone in the distal fibula.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

I.T.S. Implantat-Technologie-Systeme GmbH
% Mr. Al Lippincott
Engineering Consulting Services, Inc.
3150 E. 200th Street
Prior Lake, Minnesota 55372

FEB - 2 2007

Re: K063672
Trade/Device Name: Fibula Plate PROlock with Angular Stability
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HRS
Dated: January 24, 2007
Received: January 25, 2007

Dear Mr. Lippincott:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Barbara Melkerson
for

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

510(k) NUMBER: K063672

DEVICE NAME: **FIBULA PLATE PROLOCK WITH ANGULAR STABILITY**

INDICATIONS FOR USE:

The I.T.S. Fibula Plate PROlock with Angular Stability is a titanium implant fracture fixation system for repairing bone fractures located from the middle to the distal third of the fibula.

Indications for Use include metaphysial and diaphysial fracture fixation of acute fractures, malunions, and non-unions of the distal fibula. Other indications include corrective osteotomy and open and closed fractures.

The system is not intended for spinal use.

Prescription Use X AND/OR Over-The-Counter-Use _____

(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Number K